



PATENT  
Attorney Docket No. CNSR-07141

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen C. Suffin *et al.*

Serial No.: 10/697,497

Group No.: 1617

Filed: 10/30/2003

Examiner: Kim, J.M.

Entitled:

**Compositions And Methods For Treatment Of  
Nervous System Disorders**

**INFORMATION DISCLOSURE  
STATEMENT TRANSMITTAL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**CERTIFICATE OF MAILING UNDER 37 CFR § 1.8(a)**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 23, 2006.

By: \_\_\_\_\_

  
Christopher J. Collins

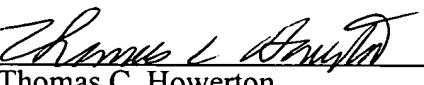
Sir or Madam:

Enclosed please find an Information Disclosure Statement and Form PTO-1449, including copies of the references contained thereon, for filing in the U.S. Patent and Trademark Office.

A check for \$180.00 is also enclosed pursuant to 37 C.F.R. § 1.17(p) for filing this Information Disclosure Statement after three months as set forth in 37 C.F.R. § 1.97(c).

The Commissioner is hereby authorized to charge any additional fee or credit overpayment to our Deposit Account No. 08-1290. **An originally executed duplicate of this transmittal is enclosed for this purpose.**

Dated: June 23, 2006



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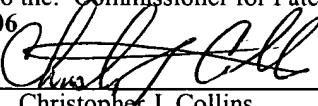
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Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- United States Patent No. 3,819,706 To Mehta;
- United States Patent No. 3,885,046 To Mehta;
- United States Patent Application No. 2002/0052341 To Fang *et al.*;
- United States Patent No. 5,512,593 To Dante;
- United States Patent No. 5,817,665 To Dante;
- United States Patent No. 6,034,091 To Dante;
- United States Patent No. 6,080,736 To Landry *et al.*;
- United States Patent No. 6,228,875 To Tsai;
- United States Patent Application No. 2002/0035145 To Tsai;
- United States Patent No. 6,239,162 To Oxenkrug;
- United States Patent No. 6,395,752 To Midha *et al.*;
- United States Patent No. 5,731,000 To Ruff *et al.*;
- United States Patent No. 5,968,553 To Maitra *et al.*;

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- United States Patent No. 6,242,496 To Kulkarni et al.;
- United States Patent No. 6,333,332 To Han et al.;
- United States Patent No. 6,306,436 To Chungi et al.;
- United States Patent No. 6,369,113 To Young;
- United States Patent No. 6,150,420 To Houdi et al.;
- United States Patent No. 6,294,192 To Patel et al.;
- United States Patent No. RE33,994 To Baker et al. ;
- United States Patent No. 6,372,252 To Blume et al.;
- United States Patent No. 6,207,190 To Richardson et al.;
- United States Patent No. 6,319,519 To Woolfe et al;
- United States Patent No. 6,287,600 To Ouali et al;
- United States Patent No. 6,284,274 To Merrill et al.;
- United States Patent No. 6,258,816 To Singh et al.;
- United States Patent No. 6,087,386 To Chen et al.;
- United States Patent No. 5,620,705 To Dong et al.;
- United States Patent No. 5,879,701 To Audett et al.:
- United States Patent No. 4,638,043 To Szycher et al.;
- United States Patent No. 5,830,505 To Fischer et al.;
- United States Patent No. 5,876,746 To Jona et al.;
- United States Patent No. 5,840,327 To Gale et al;
- United States Patent No. 6,197,827 To Cary;
- United States Patent No. 6,280,763 To Midha et al;
- United States Patent No. 5,834,011 To Rose et al.;
- United States Patent No. 5,891,461 To Jona et al.;
- United States Patent No. 5,145,682 To Chien et al.;
- United States Patent No. 6,375,979 To DiSanto et al.;
- United States Patent No. 4,931,279 To Bawa et al.;
- United States Patent No. 4,668,506 To Bawa et al. ;
- United States Patent No. 5,174,471 To Kozlowski et al.;
- United States Patent No. 5,351,858 To Bar-Yona et al.;
- United States Patent No. 4,736,849 To Leonard et al.;
- United States Patent No. Des. 335,081 To Pierantozzi et al;
- United States Patent No. Des. 358,762 To Walchek et al;
- United States Patent No. 4,165,709 To Studer;
- United States Patent No. 6,138,866 To Lambelet et al.;
- United States Patent No. 3,651,927 To Richardson et al.;

- United States Patent No. 5,770,226 To Hughes et al.;
- United States Patent No. 4,807,757 To Rappaport et al.;
- United States Patent No. 3,678,884 To Robbins;
- United States Patent No. 4,640,560 To Blum;
- United States Patent No. 6,169,707 To Newland;
- Baldessarini, "Drugs and treatment of psychiatric disorders", pp 383-419 In: Goodman and Gilman's The Pharmacological Basis Of Therapeutics, Eighth Edition, Goodman *et al.*, Eds, Permagon Press, New York (1990);
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- Stoudemire A., "Expanding Psychopharmacologic Treatment Options For The Depressed Medical Patient", *Psychosomatics*, 36(2):S19-S26 (1995);
- Andrews *et al.*, "Contemporary Management Of Depression", *Am J Med* 97(6A):24S-32S (1994);
- Baumann P., "Pharmacokinetic-pharmacodynamic relationship of the selective serotonin reuptake inhibitors", *Clin Pharmacokinet*, 31(6):444-69 (1996);
- Mischoulon *et al.*, "Strategies For Managing Depression Refractory To Selective Serotonin Reuptake Inhibitor Treatment: A Survey Of Clinicians", *Can J Psychiatry* 45(5):476-81 (2000);
- Katona C.L., "Refractory Depression: A Review With Particular Reference To The Use Of Lithium Augmentation", *Eur Neuropharmacol* 5 Suppl:109-113 (1995);
- Appelberg *et al.*, "Patients with severe depression may benefit from buspirone augmentation of selective serotonin reuptake inhibitors: results from a placebo-controlled, randomized, double-blind, placebo wash-in study", *J. Clin Psychiatry*, 62(6):448-452 (2001);
- Shelton *et al.*, "A Novel Augmentation Strategy For Treating Resistant Major Depression", *Am J Psychiatry* 158:131-134 (2001);
- Taylor D, "Selective Serotonin Reuptake Inhibitors And Tricyclic Antidepressants In Combination: Interactions And Therapeutic Uses", *Br J Psychiatry* 167:575-580 (1995);
- Shelton RC., "Treatment Options For Refractory Depression", *J Clin Psychiatry* 60 Suppl 4:57-61 (1999);

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<sup>1</sup> We have been unable to locate this reference, but if the examiner request a copy we will seek to obtain it.

- Doraiswamy *et al.*, "Quality of life in geriatric depression: a comparison of remitters, partial responders, and nonresponders", *Am J Geriatr Psychiatry*, 9(4):423-428 (2001);
- Katz S.E., "Bupropion Treatment Of Refractory Depression", *J Clin Psychiatry*, 7:51-52 (1987);
- Horst *et al.*, "Mechanisms of Action And Clinical Characteristics Of Three Atypical Antidepressants: Venlafaxine, Nefazodone, Bupropion", *J Affect Disord* 51(3):237-254 (1998);
- Bryant *et al.*, "Review of bupropion", *Clin Pharm*, 2(6):525-537 (1983);
- Rotzinger *et al.*, "Metabolism Of Some "Second"-And "Fourth"-Generation Antidepressants: Iprindole, Viloxazine, Bupropion, Mianserin, Maprotiline, Trazodone, Nefazonone, and Venlafaxine", *Cell Mol Neurobiol*, 19(4):427-442 (1999);
- Preskorn *et al.*, "Evaluation of bupropion hydrochloride: the first of a new class of atypical antidepressants", *Pharmacotherapy*, 4(1):20-34 (1984);
- Goodnick P.J., "Pharmacokinetics of second generation antidepressants: bupropion", *Psychopharmacol Bull* 27(4):513-519 (1991);
- Ascher *et al.*, "Bupropion: A review of its mechanism of antidepressant activity", *J Clin Psychiatry*, 56(9):395-401 (1995);
- Erfurth *et al.*, "Bupropion As Add-On Strategy In Difficult-To-Treat Bipolar Depressive Patients", *Neuropsychobiology*, 45 Suppl 1:33-36 (2002);
- James *et al.*, "Bupropion: overview and prescribing guidelines in depression", *South Med J* 84(2):222-224 (1991);
- Nelson J.C., "Augmentation Strategies With Serotonergic-Noradrenergic Combinations", *J Clin Psychiatry*, 59 Suppl 5:65-68 (1998);
- Fatemi *et al.*, "Venlafaxine And Bupropion Combination Therapy In A Case Of Treatment-Resistant Depression", *Ann Pharmacother* 33(6):701-703 (1999);
- Marshall *et al.*, "Paroxetine/Bupropion Combination Treatment For Refractory Depression", *J Clin Psychopharmacol*, 16:80-81 (1996);
- Pierre *et al.*, "Bupropion-Tranylcypromine Combination For Treatment-Refraactory Depression". *J Clin Psychiatry*, 61:450-451 (2000);
- Leppik I.E., "Antiepileptic drugs in development: prospects for the near future", *Epilepsia*, 35 Suppl 4:S29-40 (1994);
- May *et al.*, "Fluctuations of 10-hydroxy-carbazepine during the day in epileptic patients", *Acta Neurol Scand* 93(6):393-7 (1996);

- Pisani *et al.*, "Effects of the antidepressant drug viloxazine on oxcarbazepine and its hydroxylated metabolites in patients with epilepsy", *Acta Neurol Scand*, 90(2):130-132 (1994);
- Kristensen *et al.*, "Pharmacokinetics of 10-OH-carbazepine, the main metabolite of the antiepileptic oxcarbazepine, from serum and saliva concentrations", *Acta Neurol Scand*, 68(3):145-150 (1983);
- Larkin *et al.*, "Lack Of Enzyme Induction With Oxcarbazepine (600 mg daily) In Healthy Subjects", *Br J Pharmacol*, 31(1):65-71 (1991);
- Zakrzewska *et al.*, "Oxcarbazepine: a new drug in the management of intractable trigeminal neuralgia", *J Neurol Neurosurg Psychiatry*, 52(4):472-6 (1989);
- Borusiak *et al.*, "Hyponatremia induced by oxcarbazepine in children", *Epilepsy Res*, 30:241-6 (1998);
- Jung *et al.*, "The distribution of 10-hydroxy carbazepine in blood compartments", *Biopharm Drug Dispos* 18(1):17-23 (1997);
- Dunkin *et al.*, "Executive dysfunction predicts nonresponse to fluoxetine in major depression", *J Affect Disord*, 60(1):13-23 (2000);
- Mayberg *et al.*, "Regional metabolic effects of fluoxetine in major depression: serial changes and relationship to clinical response", *Biol Psychiatry* 48:830-843 (2000);
- Brown G.M., "Neuroendocrine probes as biological markers of affective disorders: new directions", *Can J Psychiatry*, 34:819-23 (1989);
- New *et al.*, "Serotonin and the prediction of response time to fluoxetine in patients with mild depression", *Psychiatry Res*, 88(2):89-93 (1999); and
- Zanardi et al., "Efficacy Of Paroxetine In Depression Is Influenced By A Functional Polymorphism Within The Promoter Of The Serotonin Transporter Gene", *J Clin Psychopharmacol* 20:105-107 (2000).

Applicant has become aware of the following printed publications which may be material to the examination of this application:

- Cook *et al.*, "Prefrontal Changes And Treatment Response Prediction In Depression", *Semin Clin Neuropsychiatry*, 6(2):113-20 (2001)<sup>2</sup> discusses new QEEG measures that may also identify changes in brain activity. The reference does not disclose a formulation comprising oxcarbazepine and an antidepressant.

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<sup>2</sup> We have been unable to locate a full copy of this reference, but an abstract is included.

- Cook *et al.*, "Early changes in prefrontal activity characterize clinical responders to antidepressants," *Neuropsychopharmacology*, 27(1):120-31 (2002) discusses brain region specific changes in QEEG parameters after treatment with fluoxetine or venlafaxine. The reference does not disclose a formulation comprising oxcarbazepine and an antidepressant.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: June 23, 2006

  
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<p style="text-align: center;">         FORM PTO-1449          (Modified)  <b>JUN 26 2006</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>          (Use Several Sheets If Necessary)          (37 CFR § 1.98(b))       </p>				Attorney Docket No.: CNSR-07141		Serial No.: 10/697,497	
				Applicant: Len Brandt <i>et al.</i>			
				Filing Date: 10/30/03		Group Art Unit: 1614	
U.S. PATENT DOCUMENTS							
Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	1	3,819,706	06/25/74	Mehta	260	570.5	11/30/70
	2	3,885,046	05/20/75	Mehta	424	330	08/23/73
	3	5,512,593	04/30/96	Dante	514	410	03/02/93
	4	5,817,665	10/06/98	Dante	514	282	11/20/95
	5	6,034,091	03/07/00	Dante	514	282	10/02/98
	6	6,080,736	06/27/00	Landry <i>et al.</i>	514	221	10/27/99
	7	6,228,875	05/08/01	Tsai	514	380	04/14/99
	8	6,239,162	05/29/01	Oxenkrug	514	415	04/27/00
	9	6,395,752	05/28/02	Midha <i>et al.</i>	514	317	08/11/00
	10	5,731,000	03/24/98	Ruff <i>et al.</i>	424	451	03/22/96
	11	5,968,553	10/19/99	Maitra <i>et al.</i>	424	474	12/30/97
	12	6,242,496	06/05/01	Kulkarni <i>et al.</i>	514	649	09/28/99
	13	6,333,332	12/25/01	Han <i>et al.</i>	514	276	08/25/00
	14	6,306,436	10/23/01	Chungi <i>et al.</i>	424	464	04/28/00
	15	6,369,113	04/09/02	Young	514	649	06/27/01
	16	6,150,420	11/21/00	Houdi <i>et al.</i>	514	649	01/22/99
	17	6,294,192	09/25/01	Patel <i>et al.</i>	424	451	02/26/99
	18	RE33,994	06/14/92	Baker <i>et al.</i>	424	465	08/04/89
	19	6,372,252	04/16/02	Blume <i>et al.</i>	424	464	04/28/00
	20	6,207,190	03/27/01	Richardson <i>et al.</i>	424	472	08/11/99
	21	6,319,519	11/20/01	Woolfe <i>et al.</i>	424	472	02/20/01
	22	6,287,600	09/11/01	Ouali <i>et al.</i>	424	472	03/20/00
	23	6,284,274	09/04/01	Merrill <i>et al.</i>	424	472	03/03/00
	24	6,258,816	07/10/01	Singh <i>et al.</i>	514	255	10/26/98
	25	6,087,386	07/11/00	Chen <i>et al.</i>	514	381	06/17/97
	26	5,620,705	04/15/97	Dong <i>et al.</i>	424	472	05/16/95
	27	5,879,701	03/09/99	Audett <i>et al.</i>	424	448	02/28/97
	28	4,638,043	01/20/87	Szycher <i>et al.</i>	528	75	08/23/85
	29	5,830,505	11/03/98	Fischer <i>et al.</i>	424	487	01/01/97
	30	5,840,327	11/24/98	Gale <i>et al.</i>	424	448	08/15/96
	31	6,197,827	03/06/01	Cary	514	646	11/16/99
	32	6,280,763	08/28/01	Midha <i>et al.</i>	424	448	05/10/99
	33	5,834,011	11/10/98	Rose <i>et al.</i>	424	449	06/07/98
	34	5,876,746	03/02/99	Jona <i>et al.</i>	424	449	06/06/96
	35	5,891,461	04/06/99	Jona <i>et al.</i>	424	449	09/14/95
Examiner:				Date Considered:			
<b>EXAMINER:</b> Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

FORM PTO-1449 (Modified) <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use Several Sheets If Necessary) (37 CFR § 1.98(b))				Attorney Docket No.: CNSR-07141		Serial No.: 10/697,497	
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				Filing Date: 10/30/03		Group Art Unit: 1614	

## U.S. PATENT DOCUMENTS

Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee	Class	Subclass	Filing Date
	36	Des. 358,762	05/30/95	Walchek <i>et al.</i>	D9	341	10/20/93
	37	4,165,709	08/28/79	Studer	116	308	01/24/78
	38	6,138,866	10/31/2000	Lambelet <i>et al.</i>	221	25	09/09/99
	39	6,375,979	04/23/02	DiSanto <i>et al.</i>	424	449	03/05/01
	40	4,931,279	06/05/90	Bawa <i>et al.</i>	424	427	07/21/88
	41	4,668,506	05/26/87	Bawa <i>et al.</i>	424	429	08/16/85
	42	5,174,471	12/29/92	Kozlowski <i>et al.</i>	221	154	06/10/92
	43	5,351,858	10/04/94	Bar-Yona <i>et al.</i>	221	266	11/23/92
	44	4,736,849	04/12/88	Leonard <i>et al.</i>	206	534	08/12/85
	45	Des. 335,081	04/27/93	Pierantozzi <i>et al.</i>	D9	341	07/30/91
	46	5,145,682	09/08/92	Chien <i>et al.</i>	424	448	03/08/89
	47	3,651,927	03/28/72	Richardson <i>et al</i>	206	42	10/21/69
	48	5,770,226	06/23/98	Hughes <i>et al.</i>	424	464	06/10/96
	49	4,807,757	02/28/89	Rappaport <i>et al.</i>	206	535	08/04/87
	50	3,678,884	07/25/72	Robbins	116	121	12/28/70
	51	4,640,560	02/03/87	Blum	312	234.1	12/17/84
	52	6,169,707	01/02/01	Newland	368	10	11/30/98

## U.S. APPLICATION DOCUMENTS

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53	2002/0035145		Tsai	514	472	04/13/01
54	2002/0052341		Fang <i>et al.</i>	514	58	11/16/01

## OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)

55	Baldessarini, "Drugs and Treatment Of Psychiatric Disorders", In: Goodman and Gilman's The Pharmacological Basis Of Therapeutics, Eighth Edition, Goodman <i>et al.</i> , Eds, Permagon Press, New York, Ch 18 pp.383-419 (1990)
56	Stoudemire A., "Expanding Psychopharmacologic Treatment Options For The Depressed Medical Patient", <i>Psychosomatics</i> , 36(2):S19-S26 (1995).
57	Andrews <i>et al.</i> , "Contemporary Management Of Depression", <i>Am J Med</i> 97(6A):24S-32S (1994)
58	Baumann P., "Pharmacokinetic-Pharmacodynamic Relationship Of The Selective Serotonin Reuptake Inhibitors", <i>Clin Pharmacokinet</i> , 31(6):444-69 (1996)
59	Mischoulon <i>et al.</i> , "Strategies For Managing Depression Refractory To Selective Serotonin Reuptake Inhibitor Treatment: A Survey Of Clinicians", <i>Can J Psychiatry</i> 45(5):476-81 (2000)
60	Katona C.L., "Refractory Depression: A Review With Particular Reference To The Use Of Lithium Augmentation", <i>Eur Neuropsychopharmacol Suppl</i> :109-113 (1995)
61	Appelberg <i>et al.</i> , "Patients With Severe Depression May Benefit From Buspirone Augmentation Of Selective Serotonin Reuptake Inhibitors: Results From A Placebo-Controlled, Randomized, Double-Blind, Placebo Wash-In Study", <i>J. Clin Psychiatry</i> , 62(6):448-452 (2001)
62	Shelton <i>et al.</i> , "A Novel Augmentation Strategy For Treating Resistant Major Depression", <i>Am J Psychiatry</i> 158:131-134 (2001)
63	Taylor D, "Selective Serotonin Reuptake Inhibitors And Tricyclic Antidepressants In Combination: Interactions And Therapeutic Uses", <i>Br J Psychiatry</i> 167:575-580 (1995).

Examiner:	Date Considered:
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EXAMINER:	Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.
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			Filing Date: 10/30/03	Group Art Unit: 1614	
			OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)		
64	Shelton R.C., "Treatment Options For Refractory Depression", <i>J Clin Psychiatry</i> 60 Suppl 4:57-61 (1999)				
65	Doraiswamy <i>et al.</i> , "Quality Of Life In Geriatric Depression: A Comparison Of Remitters, Partial Responders, And Nonresponders", <i>Am J Geriatr Psychiatry</i> , 9(4):423-428 (2001)				
66	Katz S.E., "Bupropion Treatment Of Refractory Depression", <i>J Clin Psychiatry</i> , 7:51-52 (1987).				
67	Horst <i>et al.</i> , "Mechanisms of Action And Clinical Characteristics Of Three Atypical Antidepressants: Venlafaxine, Nefazodone, Bupropion", <i>J Affect Disord</i> 51(3):237-254 (1998)				
68	Bryant <i>et al.</i> , "Review Of Bupropion", <i>Clin Pharm</i> , 2(6):525-537 (1983)				
69	Rotzinger <i>et al.</i> , "Metabolism Of Some "Second"-And "Fourth"-Generation Antidepressants: Iprindole, Viloxazine, Bupropion, Mianserin, Maprotiline, Trazodone, Nefazodone, and Venlafaxine", <i>Cell Mol Neurobiol</i> , 19(4):427-442 (1999)				
70	Preskorn <i>et al.</i> , "Evaluation Of Bupropion Hydrochloride: The First Of A New Class Of Atypical Antidepressants", <i>Pharmacotherapy</i> , 4(1):20-34 (1984)				
71	Goodnick P.J., "Pharmacokinetics Of Second Generation Antidepressants: Bupropion", <i>Psychopharmacol Bull</i> 27(4):513-519 (1991).				
72	Ascher <i>et al.</i> , "Bupropion: A Review Of Its Mechanism Of Antidepressant Activity", <i>J Clin Psychiatry</i> , 56(9):395-401 (1995)				
73	Erfurth <i>et al.</i> , "Bupropion As Add-On Strategy In Difficult-To-Treat Bipolar Depressive Patients", <i>Neuropsychobiology</i> , 45 Suppl 1:33-36 (2002)				
74	James <i>et al.</i> , "Bupropion: Overview And Prescribing Guidelines In Depression", <i>South Med J</i> 84(2):222-224 (1991)				
75	Nelson J.C., "Augmentation Strategies With Serotonergic-Noradrenergic Combinations", <i>J Clin Psychiatry</i> , 59 Suppl 5:65-68 (1998)				
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